

REMARKS

Applicant has now had an opportunity to carefully consider the Examiner's comments set forth in the Office Action of June 14, 2006. In the Office Action, claims 1-34 are pending with claims 1 and 18 being independent claims. By this amendment, Applicant has amended claims 1, 18, and 19. Applicant believes that all of the amendments do not introduce new matter. Review and reconsideration of the claims are respectfully requested.

Claims 1-34 remain in this application and are believed to be in proper condition for allowance.

A. Drawings

The Examiner has objected to the drawings in that: element 106 is not referenced in the detailed description, and the Prior Art drawing does not have a figure number. In response, Applicant has filed herewith replacement drawings for the Prior Art figure and FIG. 1. Specifically, the drawing previously labeled as PRIOR ART is now labeled as FIG. 1A. The drawing previously labeled as FIG. 1 has been relabeled as FIG. 1B. Further, regarding replacement drawing FIG. 1B, the reference character "106" is now properly referenced in the specification (see the amended text listed under the heading p.8, paragraph 1, lines 1-12 in the Amendments to the Specification section).

In addition to the above corrections to drawings, Applicant has filed herewith replacement drawings for FIG. 3 which now includes reference character "306a" to distinctly point out the patient's left nostril, and FIG. 4 which now includes reference characters "306a" and "306b" to distinctly point out the patients left and right nostrils respectively.

Applicant respectfully requests entry of replacement drawings FIG. 1A, 1B, 3 and 4. Applicant believes that these amendments do not contain new matter and will submit formal drawings for all figures at the appropriate time prior to issuance. Accordingly, Applicant believes that the entry of these replacement drawings renders the Examiner's objections moot, and requests that the Examiner withdraw his objections.

B. Specification

The Examiner has objected to the Specification as follows: Abstract is greater than 150 words, the use of the word Velcro should be capitalized and accompanied by generic terminology, the Prior Art drawing is not listed or disclosed, all figures are not expressly listed, and claim 19 is in improper form. Also, although not required, the Examiner suggests that a new reference number be added for a patient's nostrils and that references to certain multiple elements, e.g., 106a,b, be written as two separate elements, e.g., 106a and 106b.

In response, Applicant has amended the Abstract such that the word count is less than 150 words, has amended claim 19 to remove the improper language, and has amended the Specification to include the Examiner's required and suggested changes. That is, all references to the drawings have been included in the list of figures as well as in the detailed description, and all references to multiple elements have been separated into two elements. Furthermore, Applicant has added new element numbers 306a and 306b to replacement FIG. 3, replacement FIG. 4, and the detailed description to reference a patients left and right nostril respectively.

Applicant believe that these amendments do not contain new matter and respectfully requests entry of the amended Specification. Accordingly, Applicant believes that the entry of

these amendments renders the Examiner's objection moot, and requests that the Examiner withdraw his objections.

C. Claim Rejections

1. The Cited Art:

U.S. patent 6,418,928 to Bordewick, et al. (Bordewick) discloses a Multi-Seal Respirator Mask consisting of a nasal mask designed to seal against a patient's face, and nasal inserts also designed to seal against the two nasal openings (naris, nostrils, etc.) of the patient's nose. Bordewick incorporates by reference U.S. patent 4,782,832 to Trimble et al. (Trimble) which separately discloses the nasal inserts. The nasal inserts are "generally frustoconical in shape so as to sealingly engage the naris-defining surfaces of the nose." (Trimble, col. 2, lines 20-21; see also Bordewick, col. 3, lines 22-33.) Thus, the Bordewick nasal inserts act as plugs to seal the patient's nostrils. The invention in Bordewick works as a respirator by creating "substantially air-tight primary seals [of the nasal plugs] with the patient's nasal passages" and "a substantially air-tight secondary seal [of the nasal mask] around the patient's nose". (Bordewick, col. 2, lines 18-20). In fact, the multiple sealing mechanisms of Bordewick are required in order for the Bordewick mask to function properly as a respirator. If the Bordewick mask did not seal the patient's nostrils, then the mask would not be a respirator, but rather, it would be a conventional gas delivery system.

Although Bordewick discloses a nasal mask with sealing nasal inserts, Bordewick does not disclose or fairly suggest a nasal mask with nasal prongs that can deliver simultaneously a breathable fluid from both the internal cavity of the mask and the nasal prongs to the patient. (Disclosure, p. 4, lines 6-10). Instead, a patient using Bordewick's invention breathes solely

through the nasal plugs. The purpose of the mask in Bordewick is to form a region of intermediate pressure inside of the mask to "decrease[] the pressure differential between the interior of the mask and the outside atmosphere to reduce the gas flow rate out of the mask in the event of a leak [from the nasal plugs]". (Bordewick, col. 2, lines 4-7 and 22-25.) Therefore, it is readily apparent that the mask in Bordewick provides a respiratory mask system for a patient and does not provide a source of breathable fluid to the patient. Therefore, Bordewick differs structurally and functionally from the various embodiments of Applicant's invention.

2. The Subject Disclosure further Distinguished from Bordewick:

The nasal prongs in the various embodiments of the subject disclosure are substantially adapted to fit beyond the nasal opening and extend inside of the patient's nostrils without sealing the patient's nostrils. (Disclosure, p.4, lines 3-5; see also amended independent claims 1 and 18.) The operation of the nasal prongs of the subject disclosure do not require a "substantially-airtight seal" against the nasal openings of the patient to work effectively as required in Bordewick's invention ("any type of nasal insert capable of forming a seal with a nasal passage can be used", Bordewick, col. 3, lines 32-33.) In fact, if the nasal prongs of Applicant's invention actually sealed a patient's nostrils as in Boredewick, Applicant's mask would not function as the intended fluid, or gas, delivery system. A patient using the various embodiments of the subject disclosure may breath the delivered fluid, or gaseous material, directly from the prongs, from the prongs and the mask cavity, or even around the prongs from the mask cavity. Bordewick does not disclose or fairly suggest a nasal mask with prongs that allows a patient to breath gaseous material being delivered from both the mask and the prongs, and therefore differs structurally from the subject disclosure.

3. Claim Rejections- 35 U.S.C. §102(b) anticipation by Bordewick et al., US Pat. No. 6,418,928

The Examiner rejected claims 1-3, 12-15, 18-20, and 29-32 under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,418,928 to Bordewick et al. (Bordewick). In response, Applicant has amended independent claims 1 and 18 to more clearly distinguish the claims over the prior art.

Regarding amended independent claims 1 and 18, Applicant respectfully asserts that Bordewick does not anticipate amended claims 1 or 18. Anticipation of a claim, or lack of novelty under §102, requires that a single prior art reference contain all of the elements or limitations of the claim. *Lindemann Maschinefabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1458 (Fed. Cir. 1984). Accordingly, Applicant respectfully contends that amended independent claims 1 and 18 are not anticipated because they differ structurally and functionally from the subject matter disclosed in Bordewick.

The Examiner argues that Figures 1-3 of Bordewick disclose the critical elements of claims 1 and 18. However, although the figures alone may constitute enabling prior art as per MPEP §§ 2121.04 and 2125, "they must clearly show all claimed structural features and how they are put together". As discussed in detail above, the structure disclosed in the Bordewick figures, as well as in the specification, has nasal inserts that seal a patient's nostrils thereby preventing the patient to breath fluid directly from the mask. Because the nasal inserts 14 of Bordewick seal the nostrils at the opening, all of the breathable fluid that enters the patient's nose comes through the nasal inserts directly from the delivery tube, not from the nasal mask. In sharp contrast, Applicant's nasal prongs' outer diameters are smaller than the patients' nostrils,

thereby allowing breathable fluid to flow directly from the nasal cup, around the nasal prongs, and into the patient's nostrils.

In addition, Applicant's nasal prongs allow more fluid to flow directly into the patient's lungs. The nasal prongs extend beyond the patient's nasal opening, and when combined with the nasal mask, ensure that a patient always receives a constant flow of fluid when breathing through his/her nostrils. (Disclosure, p. 4, lines 3-10). Unlike the sealed nasal inserts of Bordewick, Applicant's nasal prongs allow fluid to pass around the nasal prongs during bodily functions such as swallowing or speaking, thereby interfering less with the patient's ability to eat or talk naturally. This illustrates further advantages of the various embodiments of the subject disclosure over the prior art. (See Disclosure, p. 3, lines 19-23.)

Furthermore, Bordewick's figures clearly show that there is a minimal protrusion beyond the nasal openings by the nasal inserts (Bordewick, fig. 1, ref. 14.), and do not clearly show the nasal prongs of the subject disclosure. When the Bordewick figures are read in light of the specification, the figures do not describe the art of making nasal prongs that extend inside of a patient's nostrils, but rather the art of using short nasal inserts that plug or seal the nasal openings. Bordewick does not suggest using a nasal prong extending into a patient's nostrils, but rather suggests that a shorter plug is more comfortable to the patient and therefore preferable (See Trimble, col. 2, lines 46-48).

In further response, Applicant has amended independent claims 1 and 18 to expressly include the limitation that the nasal prongs do not seal a patient's nostrils. Specifically, Applicant has added the limitation that the nasal prongs have "an outer diameter less than the inner diameter of the patient's nostrils" that allows low force insertion of the prongs "extending into the patient's nostrils". Applicant believes that this amendment better distinguishes these

claims over the larger diameter nasal inserts of Bordewick that plug or seal a patient's nose at the openings.

For the above mentioned reasons, Applicant respectfully asserts that amended independent claims 1 and 18 are in proper condition for allowance and requests that the Examiner withdraw his rejection.

Regarding dependent claims 2-3, 12-15, amended 19, 20, and 29-32, Applicant respectfully contends that these claims depend directly or indirectly from allowable amended independent claims 1 or 18. It is well established in patent law that allowance of a parent or base claim as patentable, results in allowance of a claim dependent upon that parent claim. *See* DONALD S. CHISUM, CHISUM ON PATENTS §7.04[2]. As discussed above, Applicant respectfully submits that amended independent claims 1 and 18 are patentably distinct from, and are not disclosed in or anticipated, by Bordewick. Therefore, because claims 2-3, 12-15, amended 19, 20, and 29-32 depend from an allowable independent claim, applicant respectfully requests that Examiner withdraw his rejection and allow these dependent claims to pass to issuance.

4. Claim Rejections- 35 U.S.C. §103 in light of Bordewick, in view of Belfer, US Pat. No. 5,018,598, Bartos, US Pat. No. 4,354,488, Sullivan, US Pat. No. 4,944,310, and Bohn et al., US Pat. No. 6,860,268

The Examiner rejects claims 16-17, and 33-34 under 35 U.S.C. 103(a) as unpatentable over Bordewick; claims 4 and 21 are rejected as unpatentable over Bordewick in view of Belfer (U.S. Patent No. 5,018,598); claims 5-7 and 22-24 are rejected as unpatentable over Bordewick in view of Bartos (U.S. Patent No. 4,354,488); claims 5, 8, 22, and 25 are rejected as unpatentable over Bordewick in view of Sullivan (U.S. Patent No. 4,944,310); and claims 9-11

and 26-28 are rejected as unpatentable over Bordewick in view of Bohn et al. (U.S. Patent No. 6,860,268).

Regarding amended independent claims 1 and 18, Applicant respectfully submits that the previous discussion regarding the patentability of amended independent claims 1 and 18 over Bordewick is equally applicable to the Examiner's rejections under 35 U.S.C. 103(a). That is, amended independent claims 1 and 18 are patentably distinct from, and are not disclosed, taught or suggested by the respiratory mask of Bordewick.

Of the cited prior art patents, only Sullivan discloses the use of non-sealing nasal tubes 8 inserted into a patient's nostrils. (See Sullivan, FIG. 3; col. 2, lines 36-39). However, as discussed above, the nasal tubes 8 of Sullivan cannot be combined with the nasal mask of Bordewick because to do so would defeat the intended purpose of Bordewick which is to provide a multi-sealed respiratory mask. Respiratory masks must have a seal on the patient's airway to function properly. Therefore, Bordewick teaches away from combining non-sealing nasal tubes with a nasal mask.

Accordingly, Applicant respectfully contends that neither amended independent claim 1 nor 18 are rendered obvious in light of Bordewick, Belfer, Bartos, Sullivan or Bohn. Independent claims 1 and 18 contain structures not disclosed, taught, or suggested by the combinations of Bordewick, Belfer, Bartos, Sullivan or Bohn. Thus, the prior art, alone or in combination, does not disclose, teach or suggest a nasal mask with non-sealing nasal prongs that allows a patient to breath a fluid simultaneously both through the nasal prongs and from the nasal mask.

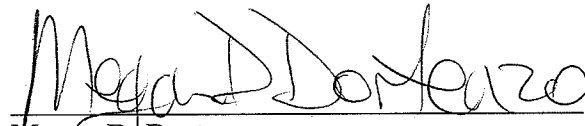
Regarding dependent claims 4-11, 16-17, 21-28, and 33-34, Applicant respectfully contends that these claims depend directly from amended independent claims 1 or 18. It is well established in patent law that allowance of a parent or base claim as patentable, normally results in allowance of a claim dependent upon that parent claim. *See* DONALD S. CHISUM, CHISUM ON PATENTS §7.04[2]. Thus, Applicant respectfully contends that claims 4-11, 16-17, 21-28, and 33-34 are not obvious in light of Bordewick, Belfer, Bartos, Sullivan or Bohn . Furthermore, because claims 4-11, 16-17, 21-28, and 33-34 depend from an allowable independent claim, Applicant respectfully asserts that these claims are in proper form for allowance. Applicant respectfully requests that Examiner withdraw his rejections and allow these dependent claims to pass to issuance.

D. Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding objections and rejections, and that they be withdrawn. Applicant believes that a full and complete response has been made to the outstanding Office Action and, as such, applicant respectfully submits that all pending claims, claims 1-34, are in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone or email the undersigned at the numbers provided.

Applicant: Gomez
Serial No.: 10/686,268

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Megan D. Dortenzo", written over a horizontal line.

Megan D. Dortenzo
Reg. No. 39,172

THOMPSON HINE LLP
10 West Second Street
2000 Courthouse Plaza N.E.
Dayton, OH 45402-1758
Phone: (216) 566-5579
Fax: (216) 566-5800
email: megan.dortenzo@thompsonhine.com